

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi v. C.R. Bard,
Case No. 2:18-cv-01320

MOTIONS IN LIMINE OPINION & ORDER NO. 33

Defendants' Motion *in Limine* ("MIL") No. 22

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence and Argument Concerning Whistleblower Letters Referencing Dr. Tillman and Related Records (Defendants' MIL No. 22, ECF No. 187), which is opposed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi (ECF No. 254). For the reasons that follow, the Court **GRANTS** Defendants' MIL No. 22.

I. Background¹

The Milanesis' case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of

¹ For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

allegations that defects in defendants’ polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.” (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages.

The relevant facts here are that Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. Mr. Milanesi had the Ventralex Large Hernia Patch implanted ten years earlier to repair a hernia.

In Defendants’ MIL No. 22, they move to exclude under Federal Rules of Evidence 403, 608, and 803 evidence of whistleblower letters and related records referencing Defendants’ expert, Dr. Tillman (Defs’ MIL No. 22, ECF No. 187.)

II. Standards

“Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*.” *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions “has developed pursuant to the district court’s inherent authority to manage the course of

trials.” *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). “The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial.” *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—“evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; see also *Koch*, 2 F. Supp. 2d at 1388 (“[A] court is almost always better situated during the actual trial to assess the value and utility of evidence.”). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401. “Irrelevant evidence is” inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 “if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court’s sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); see also *Paschal v. Flagstar Bank*,

295 F.3d 565, 576 (6th Cir. 2002) (“In reviewing the trial court’s decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.”). Hearsay is an out-of-court statement offered for the truth of the matter asserted. Fed. R. Evid. 801(a), (c). Unless a statement falls within an exception or exclusion set forth by the Federal Rules of Evidence, federal statute, or Supreme Court precedent, hearsay is inadmissible. Fed. R. Evid. 802.

III. Analysis

Defendants seek to exclude evidence concerning whistleblower letters and related records referencing Dr. Tillman. (Defs. MIL No. 22, ECF No. 187.) Both parties agree that similar issues were before this Court in the first bellwether case, *Johns v. C. R. Bard, Inc., et al.*, Case No 2:18-cv-01509. In *Johns*, the Court deferred ruling on whether the whistleblower complaints against Dr. Tillman were admissible, and the complaints ultimately were not introduced at trial. In deferring ruling on the issue of the whistleblower letters, the Court reasoned:

Dr. Tillman was accused of a manufacturer-slanted bias in employee complaints while she was at the FDA. (ECF No. 363 at PageID #18871.) Federal Rule of Evidence 702 makes clear that an expert witness’s experience and training, *i.e.* their employment, forms a part of their expertise. Fed. R. Evid. 702. But Rules 401 and 403 still apply.

...

The employment history at issue here pertains to Dr. Tillman’s tenure at the FDA, upon which she bases her expertise—a feature of her testimony that Defendants do not dispute. Thus, Dr. Tillman’s experience at the FDA would be generally relevant to her expertise. Aspects of otherwise relevant employment history, however, can be excluded under Rules 401, 402, and 403 if it is irrelevant to the expert’s expertise or their credibility. . . . [For example], if an FDA expert were accused of mishandling an interpersonal dispute between two subordinates at the FDA, it is difficult to conclude that this is relevant work history to their expert testimony about the FDA.

Here, however, Plaintiff points to complaints that Dr. Tillman had a bias toward manufacturers. The Supreme Court has defined bias as “the relationship

between a party and a witness which might lead the witness to slant, unconsciously or otherwise, [her] testimony in favor of or against a party.” *United States v. Sumlin*, 956 F.3d 879, 890 (6th Cir. 2020) (alteration in original) (quoting *United States v. Abel*, 469 U.S. 45, 52 (1984)). But courts recognize that bias may be even broader, including “[f]avor or friendly feeling toward a party [as] evidenced by . . . the witness’s conduct or expressions evincing such feeling.” 1 McCormick on Evid. § 39 (8th ed. Westlaw Jan. 2020 Update) (emphasis in original) (collecting cases); see also *Robinson v. Mills*, 592 F.3d 730, 737 (6th Cir. 2010) (explaining that “[b]ias is ‘not limited to personal animosity against a defendant or pecuniary gain.’” (quoting *Schledwitz v. United States*, 169 F.3d 1003, 1015 (6th Cir.1999))). Indeed, the Sixth Circuit has recognized the vast variety of situations from which biases may stem:

Extrinsic testimony, or that elicited by cross examination to show the bias or interest of a witness in a cause, covers a wide range and the field of external circumstances from which probable bias or interest may be inferred is infinite. The rule encompasses all facts and circumstances which, when tested by human experience, tend to show that a witness may shade his testimony for the purpose of helping to establish one side of a cause only.

Majestic v. Louisville & N.R. Co., 147 F.2d 621, 627 (6th Cir. 1945) (citations omitted).

Most importantly, “[t]he partiality of a witness is subject to exploration at trial, and is ‘always relevant as discrediting the witness and affecting the weight of his testimony.’” *Davis v. Alaska*, 415 U.S. 308, 316–17 (1974) (quoting 3A Wigmore, Evidence § 940 (Chadbourn rev. 1970)); *Schledwitz*, 169 F.3d at 1015 (“Bias is always relevant in assessing a witness’s credibility.”). And although “the Federal Rules of Evidence do not specifically so state, prior misconduct of a witness which is probative of the bias of that witness may be proved by extrinsic evidence.” *United States v. Phillips*, 888 F.2d 38, 41 (6th Cir. 1989); *Abel*, 469 U.S. at 51 (concluding that Rules 608 and 610 contemplate impeachment of a witness for bias and the inclusion of extrinsic evidence to do so). Determining the credibility of a witness, which includes “[a]ssessing the potential bias of the expert witness,” is ultimately an issue for the jury. *Cruz-Vazquez v. Mennonite General Hosp., Inc.*, 613 F.3d 54, 59 (1st Cir. 2010).

Dr. Tillman’s alleged bias in favor of manufacturers could shade her expert testimony on behalf of Defendants, making these complaints about her supposed bias relevant. Although a bias in favor of manufacturers is perhaps a less typical bias with which an expert is normally impeached, *Majestic* is clear that bias may come in many forms. Accordingly, evidence of the complaints against Dr. Tillman are not inadmissible.

Defendants’ arguments to the contrary are unsuccessful. First, they argue that this amounts to a collateral attack upon Dr. Tillman. (ECF No. 365 at PageID #18882.) But as set forth above, a witness’s bias is not a collateral matter. Next,

Defendants contend that “courts routinely exclude evidence about the prior litigation history and the disciplinary records of expert witnesses.” (*Id.* at PageID #18883 (quoting *Ferris v. Tennessee Log Homes, Inc.*, 2010 WL 1049852 (W.D. Ky. Mar. 19, 2010).) But Defendants dodge the key inquiry, which is whether that history “is of sufficiently probative value.” *Ferris*, 2010 WL 1049852, at *2. This line of cases is no bar to the admission of the complaints about Dr. Tillman because they are probative of her credibility as a witness in that the complaints address a potential bias.

Defendants then argue that courts exclude attacks on an expert’s credibility when those attacks are based on allegations and rely on extrinsic evidence (ECF No. 365 at PageID #18883–85), but this argument fails because it does not recognize the difference between bias and a character for truthfulness or mendacity. Defendants are correct that Plaintiff only references complaints against Dr. Tillman, not findings. But this is no bar to admission. Rule 608, upon which Defendants’ authorities rely, *e.g.* *United States v. Ahmed*, No. 14-cr-277 (DLI), 2016 WL 3647686, at *3 (E.D.N.Y. July 1, 2016), provides that when impeaching a witness for a character for truthfulness or untruthfulness, only reputation or opinion evidence is admissible; no extrinsic evidence is permitted except for prior criminal convictions permitted under Rule 609. Fed. R. Evid. 608. But because Plaintiff offers the complaints to impeach Dr. Tillman’s credibility by demonstrating a bias, Rule 608 and its narrow allowance of convictions as extrinsic evidence is inapplicable. *United States v. Baker*, 494 F.2d 1262, 1266 (6th Cir. 1974) (“And, although a witness's credibility generally cannot be impeached by showing arrest, indictments or other acts of misconduct not resulting in a conviction, acts demonstrating a basis for bias and prejudice may be explored to a reasonable degree.”). Thus, Plaintiff need not show that the complaints resulted in a formal finding of wrongdoing, much less a conviction. Of course, Defendants are free to point out to the jury that the FDA declined to act in response to the complaints against Dr. Tillman, which the jury may use to weigh the impeachment value of the complaints.

Although evidence of the complaints against Dr. Tillman are not clearly inadmissible at this pretrial stage, there are several issues that must be resolved prior to any admission of the complaints. Evidence of the complaints offered to show Dr. Tillman’s bias are not prohibited by Rule 608 and the complaints are clearly relevant because they go to her credibility, but the rule against hearsay and Rule 403 still apply. *Marcus & Millichap Inv. Servs. of Chi., Inc. v. Sekulovski*, 639 F.3d 301, 308 (7th Cir. 2011). At this point, the Court cannot assess whether the evidence Plaintiff intends to introduce is hearsay. Plaintiff argues that the records he will admit are “an official FDA record” (ECF No. 363 at PageID #18871), but he does not attach these records. It would be inappropriate to assess whether the complaints satisfy Rule 803(8) without the records in front of the Court.

Similarly, the probative value of this impeachment evidence in relation to the length of time it would take to present of trial and the risk of confusing the jury is unclear. Defendants provide Dr. Tillman’s affidavit, in which she explains that the complaints involve different devices, FDA advisory committees, and FDA

regulations, policies, and practices not at issue here. (ECF No. 365 at PageID #18884.) These features could unnecessarily prolong the trial. But it is difficult to determine now if this would result in an undue delay because it is unclear what these policies are and why the FDA rejected the complaints. For example, if the FDA assessed the complaints for evidence of Dr. Tillman's bias, it would be a different analysis than if the FDA simply concluded that Dr. Tillman followed FDA procedure. Moreover, the Rule 403 analysis is informed by the probative value of the impeachment evidence. Outside of the trial context, the court cannot determine what FDA expert testimony will be offered for and how much the parties will rely on it.

For these reasons, . . . the Court declines to decide whether the complaints against Dr. Tillman are ultimately admissible.

(Case No 2:18-cv-01509, MIL Order No. 8, ECF No. 390 at PageID #20906–11.) The Court adopts its prior analysis in *Johns*.

In *Johns*, it was not clear based on the parties' submissions what the FDA's reasoning was for its findings. The Court noted that "if the FDA assessed the complaints for evidence of Dr. Tillman's bias, it would be a different analysis than if the FDA simply concluded that Dr. Tillman followed FDA procedure." (*Id.* at PageID #20910–11.) While the reasons for the FDA's decision were unclear in *Johns*, in this case, Defendants submitted the FDA letter regarding the whistleblower allegations. (ECF No. 187-4.) The FDA concluded that "[t]here [was] no evidence of material violations of 21 CFR Part 10.70, other relevant rules or regulations by FDA/CDRH management," and "[t]here was no evidence of retaliation by FDA/CDRH management against complainants." (*Id.* at PageID #14031.) Additionally, in response to the whistleblower complaints, "FDA management contracted a private firm to conduct a performance audit. . . . The report issued by ICF, International favorably assessed FDA's mechanisms and abilities for settling disagreements of scientific opinion and made recommendations for further improvements to the established process." (*Id.*) Therefore, it appears that the FDA assessed the complaints for both bias and compliance with FDA procedure in rejecting the whistleblower complaints. Accordingly, the Court finds that, given that the FDA assessed the complaints for bias, the introduction of the

whistleblower complaints would lead to “mini-trials” on the issue and would cause unfair prejudice.

IV. Conclusion

For the reasons set forth above, the Court **GRANTS** Defendants’ MIL No. 22 (ECF No. 187).

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

12/13/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE